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(purged)

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461 x122
FAX: (410) 962-2219

CFN: 1125464

March 19, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Donald McGlory, President
CASCO-NERL
14 Almeida Avenue
East Providence, Rhode Island 02914

Dear Mr. McGlory:

A Food and Drug Administration (FDA) inspection conducted February 10-23, 1999 at your facility located at 3800 Dillon Street, Baltimore, Maryland, determined that your firm manufactures glucose tolerance test beverage. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation, are not in conformance with the Quality System Regulation for devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The deviations include the following:

- Failure to validate manufacturing processes and equipment.
- Failure to establish and maintain procedures for the acceptance of incoming and in-process products to assure that they meet specified requirements.
- Failure to control product that did not conform to specified requirements. Such product was distributed without documenting a justification for its use.
- Failure to establish and maintain procedures to assure that the product will not be contaminated with residues from the cleaning process.

We acknowledge that Ms. Kelly Scott, Sybron, Inc., telephoned our office on March 17, 1999 to inform us that you were in the process of replying to the observations in the FDA-483. She stated that the response would be completed within a week.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken, in addition to those addressed in your response to the FDA-483, to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosure

cc: Ms. Carol A. Valcourt
Quality Assurance Manager
CASCO-NERL Diagnostics
2800 Dillon Street
Baltimore, MD 21224